

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

To:

see form PCT/ISA/220

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

X 16331

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No  
PCT/US2004/022312

International filing date (day/month/year)  
09.08.2004

Priority date (day/month/year)  
12.08.2003

International Patent Classification (IPC) or both national classification and IPC  
A61M5/315

Applicant  
ELI LILLY AND COMPANY

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**International application No.  
PCT/US2004/022312

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material:  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing:  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2004/022312

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**Box No. II Priority**

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1. ☒ The following document has not been furnished:
- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
  - ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).
- Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-22
	No: Claims	
Inventive step (IS)	Yes: Claims	13-14
	No: Claims	1-12,15-22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

2. Citations and explanations

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2004/022312

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: WO01/95959

D2: WO99/38554

D3: EP0937471

D4: US5938642

D5: WO96/26754

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-12, 15-22 does not involve an inventive step in the sense of Article 33(3) PCT.

2.1. The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

A medication dispensing apparatus comprising:

a housing;

a drive member including a threaded shaft (fig. 1, item 4);

a fluid container with a movable piston;

a nut screwable along said drive member threaded shaft (fig. 1, items 12-13);

a screw element threadedly engaged with said housing (fig. 1, item 17);

a nut rotating element connected with said nut to be axially movable and rotatably fixed relative thereto (fig. 1, item 15), said nut rotating element rotatably fixed with said screw element when said nut rotating element and said screw element are in a first axial arrangement, said nut rotating element rotatable to said screw element when said nut rotating element and said screw element are in a second axial arrangement (page 6, lines 12-15, page 6, line 26 - page 7, line 32);

wherein during dose preparing, said nut rotating element and said screw element are in said first axial arrangement, whereby a screwing motion of said nut rotating element and screw element relative to said housing screws said nut rotating element and said screw element a first axial distance from a home position, which screwing motion of said nut rotating element screws said nut along said drive member threaded shaft a second axial distance different than said first axial distance (page 6, lines 12-15, page 6, line 26 - page 7, line 32); and

wherein during dose dispensing, said nut rotating element and said screw are in said axial arrangement, whereby a screwing motion of said screw element relative to said housing back toward said home position axially advances said nut and thereby said drive member and said fluid container piston to dispense medicine.

The subject-matter of claim 1 therefore differs from this known apparatus in that it further comprises a nut advancing plunger threadedly engaged with said screw element, said plunger axially movable and rotatably fixed relative to said housing, thereby achieving the effect of axially advancing the nut when the screw element is screwed back towards its home position. This same effect is in D1 achieved by the nut rotating element (fig. 1, item 15). To replace the arrangement of D1 with the plunger of claim 1 is a mere design option without inventive merit (Article 33(3) PCT). See also points 6-6.1 below.

3. Dependent claims 2-12, 15-22 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see documents D1-D5 and the corresponding passages cited in the search report.

4. The combination of the features of dependent claims 13-14 is neither known from, nor rendered obvious by, the available prior art.

#### **Re Item VII**

##### **Certain defects in the international application**

5. Claim 1 is not written in the two-part form (Rule 6.3(b) PCT) and none of the claims are provided with reference signs (Rule 6.2(b) PCT).

#### **Re Item VIII**

##### **Certain observations on the international application**

6. Claim 1 is not clear (Article 6 PCT). The positional and functional relationship between the different components (nut, screw element, nut rotating element, nut advancing plunger) is not sufficiently clear to enable the person skilled in the art to fully assess the functioning of the medication apparatus and the scope of the claim. This applies especially to the nut advancing plunger and its relationship to the other components.

6.1. Furthermore, it appears that the idea behind the invention is to provide a medication dispensing apparatus having a mechanical advantage (title, background of invention). However, claim 1 lacks features to provide such an apparatus. For achieving a mechanical advantage the features of claim 13 should have been present in claim 1.